



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/049,655 | 10/15/2002 | Charles L Bush JR. | P-4615.70 | 9693 |

7590 08/13/2004
Alan W Fiedler
Becton Dickinson and Company
1 Beacon Drive
Franklin Lakes, NJ 07417-1880

EXAMINER

SIRMONS, KEVIN C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3763 | |

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/049,655 | Applicant(s) BUSH ET AL. <i>on</i> | |
| | Examiner Kevin C. Sirmons | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chanoch U.S. Pat. No. 5,688,251.

Chanoch discloses a medication delivery pen comprising: a body having opposing proximal and distal ends (100); a dose control mechanism (400) disposed in the proximal end of the body (figs. 2, 3 and 6); a cartridge holder (300) having a cartridge (350) with a pierceably sealed (353) distal end, an open proximal end (301) removably attachable to the distal end of the body, and a plunger (355) in sliding fluid tight engagement within said cartridge; a drive mechanism (120) coupled between the dose control mechanism and the cartridge to exert an axial force on the plunger to inject the set dosage of medication (figs. 2 and 3), wherein the doses control mechanism (400) triggers the drive mechanism (120) to administer the injection medication held in the cartridge (figs. 2 and 3); and a mechanism (160 and lines 38-62 of claim 1) that automatically disengages the drive mechanism from the dose control mechanism to permit the use to reset the dosage on the medication delivery pen (160 and lines 38-62 of claim 1) and as to the newly amended claim 1,

Art Unit: 3763

Chanoch is fully capable of performing the function because Chanoch discloses in claim 1 that he has a means in said pen assembly for disengaging and re-engage (lines 38-62 of claim 1); as to claim 4, (see claim 1); as to claim 5, (403 has dosage indicia).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chanoch in view of Jordan et al U.S. Pat. No. 4,858,607.

Chanoch discloses the medication delivery pen substantially as claimed except for a magnifier on the body. Jordan discloses a magnifier (49) on the syringe scale. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Chanoch to have a magnifier on the body as disclosed by Jordan so that the dose setting may be better viewed (col. 3, lines 9-12).

Response to Amendment

Claim Rejections - 35 USC § 112

Applicant's amendment has overcome the 112 rejection. Therefore, the rejection has been withdrawn.

Art Unit: 3763

Specification

Applicant's amendment has overcome the objection to the specification. Therefore, the objection has been withdrawn.

Drawings

Applicant's amendment has overcome the objections to the drawing. Therefore, the objection has been withdrawn.

Response to Arguments

Applicant's arguments filed 6/15/04 have been fully considered but they are not persuasive.

In response to applicant's arguments, it is the examiner's position that after being disengaged at the predetermined position, the dose control mechanism is then free to rotate back to (forward or backward) an initial dose position where the drive mechanism and dose mechanism are then re-engaged and used to set a new dosage on the medication delivery pen (see claim 1). Note: The examiner would maintain his position that the device of Chanoch is fully capable of performing because applicant indicated that the dose control mechanism rotates forward and backward in order to set the dosage.

Note to applicant: Remember to more structure to claim 1 to overcome the prior art of record as discussed on 8/11/04.

Art Unit: 3763

Allowable Subject Matter

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.



Kevin C. Sirmons
Patent Examiner

Application/Control Number: 10/049,655

Page 6

Art Unit: 3763

8/11/04